IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
EASTERN DIVISION

DORIS SMITH,

Plaintiff,

v. No. 1:20-cv-02204-STA-jay

ZOLL MEDICAL CORPORATION, ZOLL MANUFACTURING CORPORATION, ZOLL LIFECOR CORPORATION, ZOLL LIFEVEST HOLDINGS, LLC, AND ZOLL SERVICES, LLC.,

Defendants.

ORDER PARTIALLY GRANTING AND PARTIALLY DENYING DEFENDANTS' MOTION TO DISMISS

Plaintiff Doris Smith, as the surviving spouse of Alex Smith ("the Decedent"), and as an individual, filed this wrongful death/product liability action against ZOLL Medical Corporation, ZOLL Manufacturing Corporation, ZOLL Lifecor Corporation, ZOLL LifeVest Holdings, LLC, and ZOLL Services, LLC (collectively "ZOLL"), alleging various state law claims of strict liability and negligence for the injuries and subsequent death of the Decedent.[1] Jurisdiction is predicated on diversity of citizenship, 28 U.S.C. § 1332. Defendants have filed a motion to dismiss the second amended complaint pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6) on the ground that federal law preempts all of Plaintiff's claims under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and Plaintiff has failed to state a claim upon which relief may be granted by insufficiently pleading her claims. (ECF No.

[1] Plaintiff brings her wrongful death claims pursuant to Tenn. Code Ann. §§ 20-5-106 and 20-5-110 and her product liability claims pursuant to the Tennessee Products Liability Act of 1978 ("TPLA"), Tenn. Code Ann. §§ 29-28-101 *et seq.*

30.) Plaintiff has filed a response to the motion (ECF No. 32), and Defendants have filed a reply to the response. (ECF No. 33.)[2] For the reasons set forth below, the motion to dismiss is **PARTIALLY GRANTED** and **PARTIALLY DENIED.**

When ruling on a motion to dismiss under Rule 12(b)(6), the district court must determine whether the complaint "state[s] a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when the plaintiff alleges "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plausibility requires showing more than the "sheer possibility" of relief but less than a probable entitlement to relief. *Fabian v. Fulmer Helmets, Inc.*, 628 F.3d 278, 280 (quoting *Iqbal*, 556 U.S. at 678). The mere recitation of legal elements is not enough, and the district court need not give credence to conclusory statements that are not supported by factual allegations. *Iqbal*, 556 U.S. at 678. The court must accept all facts alleged in the complaint as true and must read the complaint in the light most favorable to the plaintiff. *Lipman v. Budish*, 974 F.3d 726, 740 (6th Cir. 2020) (discussing the standard for reviewing a motion to dismiss). In a medical product liability action, under the preemption clause of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k, "a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law." *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 855 (W.D. Tenn. 2015) (quoting *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1037 (W.D. Ky. 2011)).

The Court will adopt Defendants' undisputed description of the background of the MDA. In 1976, Congress enacted the MDA, 21 U.S.C. §§ 360c *et seq.*, to the FDCA, 21 U.S.C. §§ 301 *et seq.*

[2] The second amended complaint (ECF No. 31) was filed after the motion to dismiss with Defendants' consent. Defendants have addressed the second amended complaint in their reply.

The MDA authorized the Food & Drug Administration ("FDA") to regulate medical devices, creating a comprehensive "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. Congress specified that "no State 'may establish or continue in effect with respect to a device … any requirement' relating to safety or effectiveness that is different from, or in addition to, federal requirements." *Id.* at 328 (quoting 21 U.S.C. § 360k(a)). [3]

Under the MDA, different devices receive different levels of scrutiny from the FDA. Devices are classified on a scale of I to III; Class III devices, like the ZOLL LifeVest, are those used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or which "present[] a potential unreasonable risk of illness or injury." *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 360c(a)(1)). Class III devices must receive FDA approval before they are brought to market, and they "incur the FDA's strictest regulation." *Buckman*, 531 U.S. at 343. "Premarket approval ["PMA"] is a 'rigorous'process[,]" *Riegel*, 552 U.S. at 317 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)), requiring "approximately 1,200 hours of FDA review." *Spier*, 121 F. Supp. 3d at 814 (citing *Lohr*, 518 U.S. at 477). The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 360e(d)).

The FDA's regulatory role does not end with approval of the initial PMA application. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 318 (citing 21 U.S.C. § 360e(d)(6)(A)(I)). If a manufacturer wishes to make such changes, it must submit a PMA supplement

[3] "A court considering a 12(b)(6) motion may consider materials in addition to the complaint if such are public records." *Rodney v. LaHood*, 359 F. App'x 634, 637 (6th Cir. 2010). Thus, FDA documents may properly be considered on a motion to dismiss. *See*, *e.g.*, *Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 811 n. 2 (E.D. Tenn. 2015) (taking judicial notice of "various publicly available" FDA documents).

and can implement the proposed changes only with the FDA's approval. *Riegel*, 451 F.3d at 110 (citing 21 C.F.R. § 814.39(a)). A PMA supplement is subject to the same rigorous standards of review as the initial PMA application. *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 814.39(c)).

The present action involves an FDA-approved, PMA Class III medical device — the ZOLL LifeVest wearable cardioverter defibrillator.[4] According to the second amended complaint, the Decedent was prescribed a ZOLL LifeVest by his physician due to an underlying heart condition that could "cause arrhythmia and result in sudden cardiac arrest or death." (Sec. Am. Compl. ¶ 47, ECF No. 31.) The LifeVest is designed to be worn by patients who are at risk of sudden cardiac arrest in order to provide immediate protection while the patient's physician plans for his long-term therapeutic needs. (*Id.* ¶ 29.) The LifeVest provides this protection by continuously monitoring the patient's heart rhythm and delivering treatment shocks to the patient when an arrhythmia is detected. (*Id.* ¶ 30.)

The LifeVest accomplishes this through two primary component systems: a garment and a monitor. (*Id.* ¶ 31.) The LifeVest's garment is worn underneath the patient's clothing and houses four electrocardiogram sensors along with three therapy electrodes. (*Id.* ¶¶ 31, 32.) The electrocardiogram sensors monitor the electrical signals emitted by the patient's heart, while the therapy electrodes deliver electrical shock treatments to the patient when an arrhythmia is detected. (*Id.* ¶ 32.) The four electrocardiogram sensors and three therapy electrodes are connected through a series of wires and cables to a central distribution node, which is connected to the LifeVest's monitor. (*Id.* ¶ 33.) The monitor houses the LifeVest's computer system and is worn around the patient's waist or from a shoulder strap. (*Id.* ¶¶ 31, 34.) The monitor uses proprietary software and algorithms to

[4] It is undisputed that the FDA approved the ZOLL LifeVest as a Class III Medical Device in 2001. It is further undisputed that the FDA approved multiple PMA supplements for the ZOLL LifeVest from 2001 to the present. The original and supplemental PMA approvals for the LifeVest remain in effect and have never been suspended or revoked. (Resp. pp. 3 – 4, ECF No. 32.)

interpret the electrical signals received from the patient's heart and to commence electrical shock treatment in the event of an arrhythmia. (*Id.* ¶ 34.) The LifeVest is powered by a rechargeable battery pack inserted into the monitor. (*Id.* ¶ 37.)

When the LifeVest detects a patient arrhythmia requiring electrical shock treatment, the LifeVest progresses through a treatment sequence. (*Id.* ¶¶ 35, 36.) First, the LifeVest sounds an audible alarm to determine whether the patient is responsive. (*Id.* ¶ 35.) If the patient is conscious, he has time to respond to the alarm by pressing two buttons on the LifeVest's monitor, which will terminate the treatment sequence. (*Id.*) If the patient does not respond to the alarm, the LifeVest issues an audible warning that an electrical shock is about to be administered and that bystanders should stand clear. (*Id.*) If the patient still does not respond to the alarm, the LifeVest administers an electrical shock to the patient through the therapy electrodes. (*Id.*) If the patient's heartbeat returns to normal after receiving an electrical shock, the LifeVest returns to its monitoring function. (*Id.* ¶ 36.) If the patient's arrhythmia continues, the LifeVest repeats the treatment sequence up to five times, depending on how the device was programmed by the patient's physician. (*Id.*)

Plaintiff alleges that, by receiving premarket approval for the LifeVest, Defendants are required by federal law to manufacture, produce, refurbish, and distribute every LifeVest in a condition that complies with the design specifications and manufacturing requirements approved by the FDA. (*Id.* ¶ 44.) Relevant specifications and requirements include: manufacturing, producing, refurbishing, and distributing the LifeVest with a properly functioning battery pack and battery pack charger; manufacturing, producing, refurbishing, and distributing the LifeVest with properly functioning battery pack connections, wires, cables, and battery pack retention mechanisms; manufacturing, producing, refurbishing, and distributing the LifeVest with properly functioning circuitry, software, and algorithms that will detect and treat cardiac arrhythmia; manufacturing, producing, refurbishing, and distributing the LifeVest so that it is not expired and does not contain

expired component parts, software, or algorithms; and properly testing, inspecting, refurbishing, repairing, servicing, and conducting quality assurance on the LifeVest before allowing the LifeVest to be used by a patient. (*Id.*)

By receiving premarket approval, Defendants are also required to manufacture, produce, refurbish, and distribute LifeVests in accordance with various regulations controlling proper manufacturing and production practices. (*Id.* ¶ 45.) Specifically, Defendants are prohibited from manufacturing, producing, refurbishing, or distributing any LifeVest that is "adulterated," as that term is defined by statute, *i.e.*, 21 U.S.C. § 351. (*Id.* ¶ 45(a).)

Before distributing the LifeVest to the Decedent, Defendants were in possession of the LifeVest to refurbish, repair, service, and test the device, including its battery, battery connections, wires, cables, circuitry, and software. (*Id.* ¶¶ 49, 67.) The Decedent was wearing the LifeVest on March 21, 2019, when he experienced a heart arrhythmia that required an electrical shock. (*Id.* ¶¶ 50–51.) Plaintiff claims that the LifeVest "failed to operate as designed" by not sounding an alarm or administering a shock treatment. (*Id.* ¶¶ 52–53.) The Decedent died on April 1, 2019. (*Id.* ¶ 55.)

Following the Decedent's death, Defendants immediately retrieved the LifeVest for examination. (*Id.* ¶ 56.) Plaintiff alleges that, following an investigation, it was determined that the LifeVest's battery was not properly connected at the time of the Decedent's arrhythmia and the inadequate connection contributed to the LifeVest's failure to sound an alarm and deliver an electrical shock treatment. (*Id.* ¶ 57.) Plaintiff claims that the LifeVest's failure to detect and treat the Decedent's arrhythmia is "the result of defects in the Subject LifeVest's manufacture, refurbishment, repair, production, assembly, and distribution in violation of the FDA's approved design specifications and requirements for the LifeVest." (*Id.* ¶ 59.)

The LifeVest's "defective, unsafe, and unreasonably dangerous condition actually and proximately caused injury, damage, and death" to the Decedent, according to Plaintiff. (*Id.* ¶¶ 65.)

Defendants' failure to properly manufacture, produce, refurbish, and test the LifeVest as required by the device's FDA-approved design and manufacturing requirements is allegedly what caused the LifeVest's battery to be disconnected when it reached the Decedent. (*Id.* ¶¶ 69, 70.) Plaintiff specifically contends that Defendants "performed a perfunctory, truncated, and incomplete refurbishment of the Subject LifeVest so that Zoll could place the Subject LifeVest back into the marketplace as quickly as possible in order to increase profits." (*Id.* ¶ 70.)

Plaintiff sues Defendants for strict liability and negligence due to their alleged defective manufacture, production, refurbishment, and distribution of the LifeVest in violation of the FDA-approved design and manufacturing requirements for the device.

As an initial matter, the Court notes that it agrees with Defendants that nowhere in the second amended complaint does Plaintiff allege any defect in the LifeVest other than "manufacture, refurbishment, repair, production, assembly, and distribution." And nowhere in Plaintiff's response does she suggest any alleged defect except those that fall within the "manufacturing" rubric. (Resp. p. 14, ECF No. 32 ("Mrs. Smith alleges that the FDA's premarket approval … required Defendants to manufacture, produce, refurbish, and distribute…"); ("Mrs. Smith alleges that Defendants violated the FDA's requirements … by failing to manufacture, produce, refurbish, and distribute…")). Accordingly, the motion to dismiss is granted in part. Plaintiff's claims are limited to those involving a manufacturing/refurbishing defect, and all remaining theories of recovery including "strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, …; misrepresentation, concealment, or nondisclosure, …; or under any other substantive legal theory in tort or contract whatsoever," T.C.A. § 29-28-102, not based on an alleged manufacturing/refurbishing defect, to the extent that they are alleged, are dismissed. *See Stewart v. City of Memphis*, 2017 WL 627467 at *9 (W.D. Tenn. Feb. 15, 2017) (finding that the plaintiffs' failure to address a portion of the motion to dismiss in the response constitutes a waiver of "any

argument against the dismissal of these claims"). However, the remaining portion of the motion is denied as discussed below. [5]

Defendants argue that Plaintiff's allegations are so vague and factually deficient that they do not meet the minimum pleading standards for claims cognizable under the laws of the State of Tennessee, Federal Rule of Civil Procedure 8(a)(2), *Twombly*, and *Iqbal*. Defendants correctly contend that Plaintiff's claims require, at a minimum, a showing of "facts for the Court to infer that: '(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product.'" *Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 994 (E.D. Tenn. 2016) (quoting *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008)). Defendants argue that Plaintiff has not alleged any facts demonstrating how the alleged violation caused the alleged harm.

As noted by Plaintiff, because preemption under the FDCA derives from the Supremacy Clause of the United States Constitution, courts should "first analyze whether each claim can stand under state law, and only then decide the preemption questions [when] necessary." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017); *cf. Slack v. McDaniel*, 529 U.S. 473, 485 (2000) (reciting the rule that a federal court should not reach a constitutional question if there is some other ground on which the case can be resolved). Therefore, this Court will begin its analysis with whether Plaintiff sufficiently alleges claims for strict liability and negligence under the Tennessee Protection Liability Act ("TPLA").[6]

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[5] In their motion and again in their reply, Defendants ask the Court to issue "particular findings" and state the basis for its decision if it denies the motion to dismiss. Defendants appear to be under the misapprehension that the Court does not usually support its decisions with "particular findings" nor state the basis for its decisions. Defendants are advised that this Court does, in fact, provide a factual and legal basis for all its decisions, and, thus, there is no need for Defendants to reiterate this type of request in future motions.

[6] Defendants begin their analysis with the issue of preemption and then move to the issue of whether Plaintiff has pled sufficient facts under *Iqbal/Twombly*. Under this approach or Plaintiff's

The TPLA governs all product liability actions brought under Tennessee law, whether the claim is framed in terms of strict liability or negligence. *See* Tenn. Code Ann. § 29-28-102(6).[7] A product is "defective" under the TPLA if the condition "renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code. Ann. § 29-28-102(2). It is unreasonably dangerous if it is dangerous beyond that which "would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that he knew of its dangerous condition." Tenn. Code Ann. § 29-28-102(8). It is not enough for the plaintiff to allege that he was injured by a product; he "must show that there was something wrong with the product, and trace [his] injury to the specific defect." *Maness v. Bos. Sci.*, 751 F. Supp. 2d 962, 968 (E.D. Tenn. 2010) (quoting *King v. Danek Med., Inc.*, 37 S.W.3d 429, 452–53 (Tenn. Ct. App. 2000)). Thus, as previously noted, the TPLA requires allegations demonstrating "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Mitchell v. Boehringer Ingelheim Pharm., Inc.*, 2017 WL 5617473 at *3 (quoting *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir.

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approach, which the Court has used, the ultimate issue is the same: Does the complaint sufficiently allege facts which show a plausible violation of a state law that parallels a violation of federal law?

[7]

> "Product liability action" for purposes of this chapter includes all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. "Product liability action" includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever…

Tenn. Code Ann. § 29-28-102(6)

2008)).

The Court finds that, in this case, the second amended complaint states cognizable claims under the TPLA. Plaintiff alleges claims of strict liability and negligence. Specifically, Plaintiff alleges a defect in the "manufacturing, refurbishing, repairing, servicing, producing, assembling, and distributing the subject LifeVest" which resulted in the death of the Decedent to wit: the LifeVest was defective and unreasonably dangerous because it was distributed to the Decedent in a condition where the battery was not properly connected, thus rendering the LifeVest inoperable when the Decedent needed it to perform its designed functions of monitoring his heart and providing life-saving electrical shock treatment in the event of an arrhythmia (*id.* ¶¶ 50, 56, 57, 59, 60, 63–65); the LifeVest did not sound an alarm at the time of the Decedent's arrhythmia as it was designed to do, and an examination of the LifeVest after the Decedent's death revealed the battery had not been properly connected (*id.* ¶¶ 35, 53, 56, 57); Defendants were in possession of the LifeVest for repairs and service immediately before they distributed the device to the Decedent, and Defendants performed an incomplete refurbishment in order to rush the device back to market, leading to an inference that the LifeVest's defective and unreasonably dangerous condition arose while it was in Defendants' possession (*id.* ¶¶ 49, 62–65, 67–70); and the Decedent suffered injuries, resulting in his death, due to the LifeVest's defective condition which failed to detect the Decedent's arrhythmia and deliver lifesaving treatment because of the device's disconnected battery. (*Id.* ¶¶ 50–55, 59, 60, 62, 65.)

Defendants contend that Plaintiff has provided no facts to show that the alleged battery disconnection was the result of a defect and not the result of an intentional or purposeful disconnection of the battery. Plaintiff is not required to present facts at this juncture to prove her allegations.[8] Instead, she must point to facts that plausibly support her claims, and this she has done.

[8] Defendants' "lack of proof" argument is better suited in a motion for summary judgment.

She has alleged that the Decedent was wearing the LifeVest when he had an arrhythmia, an alarm should have sounded along with a subsequent shock, the LifeVest did not work as it was intended to work because the battery was disconnected, a later investigation showed that the battery had not been properly connected, and the Decedent died as a result. These allegations meet the plausibility standard of *Twombly* and *Iqbal*. Accordingly, Defendant's motion to dismiss on this ground is denied.

Next, the Court must decide whether Plaintiff's claims are preempted under the MDA. The standard of review for a motion to dismiss in the context of MDA preemption is "more difficult than it would be in a typical product liability case." *White*, 818 F. Supp. 2d at 1037.

> When facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law. This additional step requires some greater specificity in the pleadings. However, our appellate courts have been unable to agree upon the precise level of that specificity. Nonetheless, in this Court's view, a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555, 127 S. Ct. 1955.

White, 818 F. Supp. 2d at 1037.

The MDA provides for two types of federal preemption that limit the claims that can be brought against manufacturers of PMA-approved medical devices. First, the MDA includes the following express preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d). Thus, the MDA expressly preempts claims that would impose a state-law requirement that is "different from, or in addition to" the federal

requirements imposed through the FDA's PMA process. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 316, 323. Additionally, 21 U.S.C. § 337(a) prohibits private enforcement of the FDCA. It provides that actions to enforce the FDCA "shall be by and in the name of the United States." *Id.* As such, private lawsuits that attempt to enforce the FDCA's provisions are impliedly preempted. *Buckman*, 531 U.S. at 352 (recognizing that the FDCA is "enforced exclusively by the Federal Government.").

Express and implied preemption combined leave a "narrow gap" through which a plaintiff may state a claim for injuries caused by a medical device. *Hafer*, 99 F. Supp. 3d at 857 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)("*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.")). Thus, Plaintiff's claims are preempted unless she properly alleges a parallel claim that fits through the "narrow gap" left by *Riegel* and *Buckman*. Defendants contend that Plaintiff's claims are both expressly preempted under 21 U.S.C. § 360k(a) and impliedly preempted under 21 U.S.C. § 337(a).

The *Riegel* Court established a two-step procedure for determining if state-law claims are expressly preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Riegel*, 552 U.S. at 321. If so, then the court must determine whether plaintiff's state-law claims would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements, *id.*, and relate to either the "safety or effectiveness" or "any other matter included in a requirement applicable to the device under [the MDA]," 21 U.S.C. § 360k(a). If both conditions are satisfied, the claim is preempted. *Spier*, 121 F. Supp. 3d at 816.

Claims involving a PMA device, such as the LifeVest, automatically satisfy the first condition. "Premarket approval … imposes [federal] 'requirements'" as that term is used in § 360k(a), leaving no room for courts or juries to second-guess the approval of individual devices.

Riegel, 552 U.S. at 321. That is, plaintiffs may not bring state-law claims challenging the design, manufacturing process, or labeling of a medical device that has been approved by the FDA via the PMA process. The *Hafer* Court explained the second condition as follows.

> Second, the Court must consider whether the state law claims impose any requirements "different from, or in addition to" the federal requirements. *Caplinger* [*v. Medtronic, Inc.*], 921 F.Supp.2d [1206, 1213 (W.D. Okla. 2013] (citing *Riegel*, 552 U.S. at 322–23, 128 S. Ct. 999). "State law tort duties ... impose 'requirements' applicable to the device." *Hawkins v. Medtronic*, Inc., No. 1:13–CV–00499 AWI SKO, 2014 WL 346622, at *3, 2014 U.S. Dist. LEXIS 11779, at *8–9 (E.D. Cal. Jan. 30, 2014) (citing *Riegel*, 552 U.S. at 323–24, 128 S. Ct. 999); *see also Houston* [*v. Medtronic, Inc.*], 957 F. Supp. 2d [1166, 1174 (C.D. Cal. 2013] ("'State tort law ... disrupts the federal scheme no less than state regulatory law to the same effect.'" (quoting *Riegel*, 552 U.S. at 324–25, 128 S. Ct. 999)). If the state law claim merely parallels federal requirements, express preemption does not apply. *Riegel*, 552 U.S. at 330, 128 S. Ct. 999; *see also* [*Medtronic, Inc., v.*] *Lohr*, 518 U.S. [470, 495 (1996)], 116 S. Ct. 2240 ("[N]othing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Houston*, 957 F. Supp. 2d at 1174 (citing *Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir.2005)).

Hafer, 99 F. Supp. 3d at 856.

Here, Plaintiff alleges that Defendants violated the FDA's requirements by failing to manufacture, produce, refurbish, and distribute the LifeVest with a properly functioning battery pack, charger, wires, cables, battery pack retention mechanisms, circuitry, and software and by failing to conduct adequate testing and quality assurance on the LifeVest following refurbishment and before distribution to the Decedent. Plaintiff further alleges that these violations caused the LifeVest's battery to be disconnected when it reached the Decedent, thereby rendering the device defective in its manufacture and unreasonably dangerous for its designed use.

Plaintiff does not (and cannot) sue Defendants for any purported deficiency in the design or manufacturing specifications approved by the FDA for the LifeVest. To the contrary, Plaintiff sues Defendants for allegedly failing to manufacture, produce, refurbish, and distribute the LifeVest in

compliance with its design and manufacturing specifications. Plaintiff alleges that, had Defendants properly manufactured and refurbished the LifeVest in accordance with the FDA's premarket approval requirements for the device, the Decedent would not have died. Defendants' alleged failure not only violates the FDA's requirements for the LifeVest, Defendants' failure breaches the parallel duties under Tennessee law that Defendants not manufacture, produce, or distribute the LifeVest in a defective or unreasonably dangerous condition. *See* Tenn. Code Ann. § 29-28-105(a) ("A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.")

Plaintiff points out that it appears that Defendants suggest that reference to Defendants' violation of the good manufacturing practices in the second amended complaint form the basis of Plaintiff's claims.[9] Although Plaintiff alleges that Defendants violated and deviated from the FDA approved, device specific requirements for the LifeVest when manufacturing, producing, refurbishing, and distributing the LifeVest (Sec. Am. Compl. ¶ 60, ECF No. 31), her allegations, if proved, merely bolster her claims of negligence and product defect - they do not provide their basis. *See Purchase v. Advanced Bionics, Inc.*, 896 F. Supp. 2d, 694, 699 (W.D. Tenn. 2011) ("This is not to say that Plaintiffs are precluded from introducing evidence with regard to Advanced Bionics' general manufacturing procedures and practices. Such evidence may be used, for example, to demonstrate Advanced Bionics' negligence.").

Plaintiff has specifically alleged that the FDA's premarket approval of the LifeVest required Defendants to manufacture, produce, refurbish, and distribute the LifeVest with a properly functioning battery pack, charger, wires, cables, battery pack retention mechanisms, circuitry, and

[9] *See* 21 C.F.R. §§ 820.1–820.250 (describing the scope and applicability of "good manufacturing practice requirements" of the Food and Drug Administration).

software and to conduct adequate testing and quality assurance on the LifeVest following refurbishment and before distributing the device to a new patient. In addition to these requirements, the FDA's premarket approval order for the LifeVest confirms that "[c]ommercial distribution of a [LifeVest] that is not in compliance with these conditions is a violation of the [FDCA]." (Mot. Exb. p. 2, ECF No. 30-1). Thus, Plaintiff bases her claims on Defendants' alleged failure to manufacture, produce, refurbish, and distribute the LifeVest in compliance with the FDA's design and manufacturing requirements governing the device which caused the LifeVest to be "in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller," Tenn. Code Ann. § 29-28-105, and resulted in the death of the Decedent.

The issue of preemption was addressed in *Godelia v. Doe 1*, 881 F.3d 1309 (11th Cir. 2018), another case in which a patient died when an allegedly defectively manufactured Zoll LifeVest failed to administer an electric shock when a treatable event was detected. *Id.* at 1315. The *Godelia* court described the allegations as follows:

> Mr. Godelia's complaint raises two claims based on a manufacturing defect: strict products liability and negligence. Mr. Godelia says his wife's LifeVest "was defective and unreasonably dangerous as a result of a manufacturing defect." He also says that the "manufacturing defect was the direct result of ZOLL's failure to comply with applicable federal regulations noted above for manufacturing LifeVest devices, including the subject LifeVest, and for detecting and fixing manufacturing defects with LifeVest devices before placing them into the stream of commerce."

Id. at 1318-19.

The Eleventh Circuit held in pertinent part that the plaintiff's state law claims arising out of Defendants' failure to manufacture the LifeVest in compliance with the FDA's premarket approval requirements were not expressly preempted. *Id.* at 1319–20. The court specifically determined that the plaintiff "need not state in his complaint the precise defect that caused [the] LifeVest to malfunction." *Id.* at 1318. *See also Brackin v. Medtronic, Inc.*, 2017 WL 5957204 at *7 (W.D. Tenn. Sept. 14, 2017) (rejecting the defendants' argument that "Plaintiff fails to identify any specific

defect in the design, manufacture or labeling of the [system]" because "it is not necessary for Plaintiff to pinpoint the exact mechanism by which the insulin delivery system malfunctioned. This is particularly true because the type of harm that occurred is of a kind that would only be expected to occur in the presence of a defect." (citations omitted)).

Defendants correctly point out that *Godelia* was governed by Florida's product liability laws and had somewhat different facts and allegations than those in the present case. For example, the LifeVest in *Godelia* was operational at the time of the patient's arrhythmia, while the Decedent's LifeVest was allegedly powered off at the time of his arrhythmia. And, the issue in *Godelia* was whether that LifeVest appropriately treated the patient after detecting her arrythmia and sounding an alarm, while the issue here is why the Decedent's LifeVest was allegedly powered off. However, this Court finds the *Godelia* Court's analysis of the preemption issue, while not binding, to be persuasive.

The *Brackin* Court also found that the plaintiff had sufficiently pled a parallel claim.

> Plaintiff alleges that Pamela Brackin died from complications related to an alleged insulin overdose (ECF No. ¶¶ 30–36), and — on the face of the First Amended Complaint — the insulin delivery system manufactured by the Defendants is the likely source. *See Kelley v. Howard Berger Co., Inc.*, 13-96-DLB-HBG, 2013 WL 4014748 at *2–3 (E.D. Tenn. Aug. 6, 2013) (plaintiff identified a "specific" product defect where Plaintiff alleged that equipment supplied by Defendant "leaked oxygen" and lacked "proper safety mechanisms ... that would prevent oxygen from leaking"); *Oblak v. Integra LifeSciences Corp.*, 1:16-CV-132, 2017 WL 1831098 at *3 (N.D. Ohio May 4, 2017) ("While [Plaintiff] alleges generally that one or more pieces of medical hardware ... failed, discovery will serve to clarify the exact nature and cause of the hardware failure.").

Brackin, 2017 WL 5957204 at *7. The Court in this case finds that, as in *Bracken,* the second amended complaint does not "conclusively establish that all of Plaintiff's products liability claims must fail. Even assuming that the [product] is subject to federal "requirements" within the meaning of *Riegel*, … Plaintiff has pled parallel claims sufficient to give Defendants "fair notice," *Twombly*, 550 U.S. at 555, and to push [his] claims "across the line from conceivable to plausible." *Brackin*,

2017 WL 5957204 at *7 (some citations omitted).

Because Plaintiff's product liability claims are based on Defendants' parallel duty under state law not to manufacture, refurbish, produce, and distribute a defective and unreasonably dangerous LifeVest, the Court finds, at this juncture, that Plaintiff's claims are not expressly preempted.

Defendants also contend that Plaintiff's claims are impliedly preempted. Implied preemption derives from the provision that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Intended to prohibit private citizens from filing so-called "fraud-on-the-FDA" claims, § 337(a) mandates that only the FDA has the power to police its regulation of medical devices. *Buckman*, 531 U.S. at 352. Any state law claim brought for the sole purpose of privately exercising the FDA's regulatory power with respect to a medical device like the LifeVest is impliedly preempted, while a state law claim that is not brought for this purpose is not impliedly preempted. *See Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013) ("If the claim would not exist in the absence of the FDCA, it is impliedly preempted."). Defendant's argument that Plaintiff's claims are impliedly preempts hinges on a determination by the Court that, "in the absence of a legitimate parallel claim, Plaintiff's allegations are an attempt to enforce the FDCA, so they are impliedly preempted under *Buckman* and its progeny." (Mot. p. 18, ECF No. 30.) Because the Court has found that Plaintiff has alleged a "legitimate parallel claim," Defendants' implied preemption argument fails.

Additionally, as pointed out by Plaintiff, she does not sue Defendants in an attempt to privately exercise the FDA's regulatory power under the FDCA. Rather, Plaintiff brings her claims under Tennessee state law to recover for her husband's injuries and death allegedly caused by Defendants' defective manufacture, production, refurbishment, and distribution of the Life Vest. The duties Plaintiff seeks to enforce are traditional state law duties Defendants owe as the manufacturers of the LifeVest, not duties Defendants owe to the FDA. As such, Plaintiff's claims would exist in

the absence of the FDCA and are, therefore, not impliedly preempted.

The portion of Defendants' motion seeking the dismissal of Plaintiff's claim for punitive damages under Tennessee law is also denied. Defendants contend that Plaintiff has not alleged sufficient facts to support her claim. In Tennessee, a plaintiff is entitled to recover punitive damages when she proves that the defendant acted maliciously, intentionally, fraudulently, or recklessly. Tenn. Code Ann. § 29-39-104(a)(1) ("Punitive damages may only be awarded if the claimant proves by clear and convincing evidence that the defendant against whom punitive damages are sought acted maliciously, intentionally, fraudulently or recklessly….") A defendant acts recklessly when the defendant "is aware of, but consciously disregards, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances." *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992). To sufficiently allege a claim for punitive damages, a plaintiff need only plead "sufficient factual matter to support a plausible inference that Defendant[s] acted with conscious disregard for a substantial and unjustifiable risk." *A.K. ex rel. Kocher v. Durham Sch. Servs., L.P.*, 2016 WL 11248525 at *3 (W.D. Tenn. Aug. 16, 2016).

In the present case, Plaintiff has alleged that the LifeVest was designed, manufactured, and given to her husband for the purpose of saving his life in the event he experienced an arrhythmia. As part of the FDA's premarket approval for the LifeVest, Defendants were required to refurbish, repair, service, test, and inspect the LifeVest before distributing the device to the Decedent in order to ensure its continuing functionality and safety. Rather than comply with the FDA's requirements for the device, Defendants allegedly instead chose to "perform[] a perfunctory, truncated, and incomplete refurbishment of the LifeVest so that [Defendants] could place the Subject LifeVest back into the marketplace as quickly as possible in order to increase profits." (Sec. Am. Compl. ¶¶ 69, 70, ECF No. 31.) The Decedent allegedly died as a result of Defendants' decision to elevate its profits over

consumer safety which equates to "a conscious disregard for a substantial and unjustifiable risk." The Court finds that these facts are sufficient to support Plaintiff's claim for punitive damages.

Finally, Defendants contend that the Court should dismiss Plaintiff's loss of consortium claim. In Tennessee, a spouse's action for loss of consortium is a distinct cause of action created by statute. *See* Tenn. Code Ann. § 25-1-106 ("There shall exist in cases where such damages are proved by a spouse, a right to recover for loss of consortium.")

> Consortium is defined as "the conjugal fellowship of husband and wife, and the right of each to the company, cooperation, affection and aid of the other in every conjugal relation." *Manning v. Altec, Inc.*, 488 F.2d 127, 132 (6th Cir. 1973). In Tennessee, it is "derivative" of the claims of the injured spouse. *Tuggle v. Allright Parking Sys., Inc.*, 922 S.W.2d 105, 108 (Tenn. 1996). That is, the spouse's physical injuries and incapacities are what create the claim for loss of consortium. *Hunley v. Silver Furniture Mfg. Co.*, 38 S.W.3d 555, 557 (Tenn. 2001); *Clark v. Shoaf*, 209 S.W.3d 59, 61 (Tenn. Ct. App. 2006), *perm. app. denied* (Sept. 25, 2006); *Jackson v. Miller*, 776 S.W.2d 115, 117 (Tenn. Ct. App. 1989), *perm. app. denied* (May 30, 1989).

Tangradi v. Baptist Mem'l Hosp. of Union City, 2012 WL 2681806 at *8 (W.D. Tenn. July 6, 2012).

In the present case, since Plaintiff's product liability claims survive Defendants' motion, so does her claim for loss of consortium.

In summary, because Plaintiff's state law claims based on the alleged defective manufacture/refurbishment of the LifeVest in violation of the FDA-approved design and manufacturing requirements for the device are not expressly or impliedly preempted, Plaintiff will be allowed to proceed on her state law strict liability and negligence claims concerning the manufacture/refurbishment of the LifeVest, including her claims for consortium and punitive damages, and Defendant's motion is **DENIED** on these claims.

Defendant's motion is **GRANTED** on all other claims brought by Plaintiff.

IT IS SO ORDERED.

s/ S. Thomas Anderson
S. THOMAS ANDERSON
CHIEF UNITED STATES DISTRICT JUDGE

Date: December 8, 2020.